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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,545	09/30/2003	Jason Fox	50623.00286 (ACS 3956)	7658

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EXAMINER

EDWARDS, LAURA ESTELLE

ART UNIT PAPER NUMBER

1734

DATE MAILED: 04/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/676,545	FOX ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Laura Edwards	1734	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 January 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,10 and 12-28 is/are pending in the application.
- 4a) Of the above claim(s) 17-21 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,2,10-13,22-26 and 28 is/are allowed.
- 6) ☒ Claim(s) 14-16 and 27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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***Established State of the Stent Coating Art***

It is well established and conventional in the medical and/or stent coating art to utilize a catheter or stent delivery device to hold a stent while the stent is coated with coating material. The catheter thereby serves dual purpose of a workholder and delivery device as evidenced by Rosenbluth (US 4,893,623), see col. 13, lines 34-42.

***Election/Restrictions***

This application contains claims 17-21 drawn to a non-elected invention nonelected. A complete reply to the rejection should include cancellation of non-elected claims or other appropriate action.

***Claim Rejections - 35 USC § 112***

Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 16, line 1, "the support member" lacks antecedent basis.

***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 14 and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Hemerick et al (US 7,011,675).

Hemerick et al teach a stent workholder or delivery device capable of supporting or holding a stent during coating, the workholder including a mandrel base (105), a pull rod (104) including a projecting handle or lever (116), the rod configured to move in and out of the mandrel base, and the support element (117) integrated with the rod, the support element having a first position of being engaged with an end portion of the stent and a second position being disengaged from the stent, wherein movement of the rod in and out of the mandrel base causes engagement and disengagement of the support element with the stent.

Claim 27 is rejected under 35 U.S.C. 102(e) as being anticipated by Boulais (USPAP 2004/0213893).

Boulais teaches a masking element (1) configured to be inserted through a bore of a stent, the masking element having an expanded configuration and a retracted configuration; and an expansion causing mechanism (col. 4, [0024]) capable of expanding the masking element from the retracted configuration to the expanded configuration to cause the masking element to make contact with and mask an inner surface of the stent during coating.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whittenberger et al (US 6,575,933) in view of Rosenbluth (US 4,762,128) or Boulais (PAPUS 2004/0213893).

Whittenberger et al teach a balloon type catheter capable of supporting or holding a stent (102) during coating, the workholder including a mandrel base (205/230), a pull rod or wire (217), the pull rod or wire being connected to a switch or lever (see col. 6, lines 30-43), the pull rod or wire configured to move into and out of the mandrel base, and a support element (215, 220) integrated with the rod, the support element having a first expanded position and a second unexpanded position. Whittenberger et al are silent concerning the tubular support element being expandable/retractable so as to define a workholder and/or fixture for a stent to be mounted and coated thereon. However, it was known in the art, at the time the invention was made, to provide an expandable hollow tubular member as a workholder and/or fixture for a stent during coating as evidenced by either Rosenbluth (see col. 13, lines 34-42) or a masking workholder and/or fixture when coating the stent as evidenced by Boulais (see col. 4, [0029]). In light of the teachings of either Rosenbluth or Boulais, it would have been obvious to one of ordinary skill in the art to utilize the balloon type catheter of Whittenberger et al as a stent workholder and/or fixture for enabling coating of the stent prior to delivery into the body as well as enable masking of the stent to avoid bridging of coating material across stent lattice openings.

***Allowable Subject Matter***

Claims 1/2, 10/12, 13, 22/23, 24, 28, and 25-27 would be allowable.

Claims 22-24 and 28 would be allowable because there is no teaching or suggestion in the prior art of a stent mandrel fixture comprising the combination of a masking element configured to be inserted through a bore of a stent, the masking element having an expanded configuration and a retracted configuration; and an expansion causing mechanism capable of expanding the masking element from the retracted configuration to the expanded configuration to cause the masking element to make contact with and mask an inner surface of the stent, wherein the expansion causing mechanism comprises a hollow rod in fluid communication with the masking element; a source for supplying a gas or fluid into the hollow rod to cause the masking element to expand; a rod supporting the masking element; and a lock member on the rod, the lock member acting to prevent lateral movement of the masking element.

Claim 25 would be allowable because there is no teaching or suggestion in the prior art of a stent mandrel fixture comprising the combination of a masking element configured to be inserted through a bore of a stent, the masking element having an expanded configuration and a retracted configuration; and an expansion causing mechanism capable of expanding the masking element from the retracted configuration to the expanded configuration to cause the masking element to make contact with and mask an inner surface of the stent, wherein the expansion causing mechanism comprises a first member; a second member extending out from the first member, such that the masking element is positioned over the second member, the masking element having one end secured to the second member and an opposing end secured to the first member; and a toggle switch to drive the second member into the first member which causes lateral compression and radial expansion of the masking element.

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Claim 26 would be allowable because there is no teaching or suggestion in the prior art of a fixture to support a stent during the application of a coating composition to the stent comprising the combination of a hollow tubular member configured to be inserted into a longitudinal bore of a stent; a rod extending through the tubular member; and a mechanism to cause the tubular member to expand and retract to support the stent during the application of a coating composition to the stent, wherein one end of the tubular member is attached to the rod, wherein the mechanism is configured to push an opposing end of the tubular member towards the end of the tubular member attached to the rod so as to cause the tubular member to expand outwardly to engage an inner surface of the stent.

#### ***Response to Arguments***

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.


#### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura Edwards whose telephone number is (571) 272-1227. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chris Fiorilla can be reached on (571) 272-1187. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Laura Edwards  
Primary Examiner  
Art Unit 1734

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March 31, 2006